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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,438	12/03/2001	Liming Yu	TNX95-02ABB	8540

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	**PAPER NUMBER**
1646	
MAIL DATE	**DELIVERY MODE**
06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/005,438	YU ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-22* is/are pending in the application.

4a) Of the above claim(s) *17 and 20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-16,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Re: Yu et al.

Date of Priority: 10/15/1999 (US 09/418,734)

DETAILED ACTION

Applicants' response filed on 04/10/2007 is acknowledged and fully considered.

Status of Application, Amendments, And/Or Claims

The amendments of claim 14 have been made of record.

Claims 14-22 are pending.

Claims 17 and 20-22 are withdrawn from consideration as not directed to the elected invention.

Claims 14-16, and 18-19 are under examination.

Response to Arguments

Claim Rejections-withdrawn

Claim Rejections - 35 USC § 112,second paragraph

The rejection of claim 14 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicants' amendment of claim 14.

Claim Objections/Rejections-maintained

Claim 19 remains objected for reciting "claims 14-18" which is inclusive of a withdrawn claim (i.e., claim 17) for the reasons of record on page 3 of the previous Office Action of 1/10/2007 and because Applicants want that this objection be held in abeyance until allowable subject matter is determined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14 and 18-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Landolfi (IDS, U.S. Patent 5, 349,053) and Frincke (IDS, EP 467416) in further view of Blatt (US Patent No. 5,373 808, 12/13/1994).

Claims 14 and 19 are drawn to an IFN-Fc hybrid molecule comprising an interferon molecule joined at one end to one chain of an immunoglobulin Fc fragment without any linker between the interferon and the immunoglobulin Fc fragment (claim 14), and a composition comprising the hybrid for treating tumors (claim 19). Claim 18 is drawn to the interferon molecule of Claim 14 wherein the interferon molecule is interferon-α2a or interferon-α2b.

Applicants argue (page 4 of Response) that (i) before a reference can even be considered to constitute legally cognizable prior art, it must be enabling i.e., the reference must teach how to make what it discloses, (ii) the office does not address on the issue of enabling a genus of lyphokine(LK) raised during the prosecution of the Landolfi patent (page 5), (iii) the office has pieced together references using Applicant's specification as a guide (page 6 of Response), (iv) Landolfi's motivation to solve the problem was different than increasing the serum half life of the hybrid molecule (page

6), and (v) regardless of the case of obviousness, because applicants demonstrate unexpected results over the prior art, the invention is non-obvious (page 7).

Applicant's arguments have been fully considered but they are not persuasive because the reference Landolfi teaches making chimeric molecules (immunoligands) that comprise a portion of any ligand linked to the constant region of an immunoglobulin (column 4, lines10+). Landolfi teaches that virtually any naturally occurring ligand, including lymphokines or a portion thereof could be used to make a hybrid with Fc region of an immunoglobulin (col.4, lines 56-60).

In response to applicant's argument that the motivation of Landolfi for making a hybrid (immunoligand) is different than to improve the serum half life, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Landolfi's teachings such as to increase in specificity or being suitable for pharmaceutical applications (col. 2, lines 30+) when combined with the teachings of Frincke et al where an interferon and anti-interferon antibody complex increases the half-life of the interferon to more than twelve times as compared to interferon alone, would have been obvious to one of ordinary skill in the art to make a chimeric between interferon and Fc of an immunoglobulin.

In response to applicant's argument that the instant application demonstrates unexpected results and therefore the invention is non-obvious have been fully considered but they are not persuasive because the unexpected result that the specification discloses in Example I, (see page 7 of Response) is in reference to a hybrid IFN-Fc that has a linker between IFN and Fc molecules. The specification discloses:

> "However, in an in vivo pharmacokinetic study in primates, the serum half-life of the claimed **new hybrid** was about 40 fold longer than the unmodified interferon. Also, the clearance half-life after subcutaneous (s.c.) administration of the hybrid was almost 120 fold longer."

It is noted that the **new hybrid** comprises a linker having the sequence: Gly Gly Ser Gly Gly Ser Gly Gly Gly Gly Ser Gly Gly Gly Gly Ser (SEQ ID NO: 11) in between IFN and Fc polypeptides. The instantly claimed invention is not drawn to a hybrid that comprises a linker (of SEQ ID NO: 11) in between IFN and Fc molecules. Therefore, applicants arguments are not persuasive.

Applicant's arguments that the office did not address on issues that were raised in Landolfi's application have been fully considered but they are not persuasive because each patent application is examined on its own merits.

Further, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claim 15 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Frincke et al and Landolfi in view of Blatt as applied to claims 14 and 18-19 above, and further in view of Capon et al (US Patent No. 5,116,964).

Claim 15 is further drawn to an IFN-Fc hybrid molecule wherein the interferon is joined at its C-terminal end to the N-terminal end of the immunoglobulin Fc fragment.

Applicants argue that the rejection should be withdrawn because the office has not established a prima facie case of obviousness for the primary reference.

Applicant's arguments have been fully considered but they are not persuasive because the Examiner has established that the instant invention would have been prima facie obvious to one of ordinary skill in the art over the combined teachings of Frincke et al, Landolfi as discussed above, and further, for the reasons of record on pages 7-8 of the Office Action of 1/10/2007.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landolfi and Frincke et al in view of Blatt et al as applied to claim 14 and 18-19 above, and further in view of Freeman et al (US Patent No. 6,130,316).

Claim 16 is further drawn to an IFN-Fc hybrid molecule wherein the Fc fragment is a gamma-4 chain Fc fragment, and wherein said Fc fragment does not induce ADCC or activate complement.

Applicants argue that the rejection should be withdrawn because the office has not established a prima facie case of obviousness for the primary reference. Applicant's arguments have been fully considered but they are not persuasive because the Examiner has established that the instant invention would have been prima facie obvious to one of ordinary skill in the art over the combined teachings of Frincke et al, Landolfi as discussed above, and further, for the reasons of record on pages 8-9 of the Office Action of 1/10/2007.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra, Ph.D.
Art Unit 1646
30 May 2007
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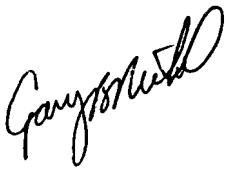

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